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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/019,963 | 03/28/2002 | Klaus Rehfeldt | 199at07.us | 6255 |
| 23416 | 7590 | 03/09/2004 | EXAMINER | |
| CONNOLLY BOVE LODGE & HUTZ, LLP P O BOX 2207 WILMINGTON, DE 19899 | | | QIAN, CELINE X | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1636 | |

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/019,963

Applicant(s)

REHFELDT ET AL.

Examiner

Celine X Qian

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Art Unit: 1636

DETAILED ACTION

Claims 1-27 are pending in the application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5 and 13, drawn to a protein toxin obtained from *Williposis californica* and or *Zygosaccharomyces bailii*.

Group II, claim(s) 6-11, drawn to a nucleic acid encoding a glucanase/protein toxin.

Group III, claim 12, drawn to a method for preparation of the nucleic acid encoding a glucanase/protein toxin.

Group IV, claim 14, drawn to a process for the preparation of the polypeptide with an amino acid sequence in accordance with SEQ ID NO:1 or NO:2.

Group V, claims 15 and 16, drawn to an antibody against the protein toxin and a method of making said antibody.

Groups VI-VIII, claims 17 and 18, drawn to a drug product comprising a nucleic acid encoding a glucanase (VI), a polypeptide (VII), or an antibody against the protein toxin (VIII).

Groups IX-XI, claims 19 and 20, drawn to a diagnostic comprising a nucleic acid encoding a glucanase (IX), a polypeptide (X), or an antibody against the protein toxin (XI).

Groups XII, claim 21 and 22, drawn to an assay for identifying functional interactors comprising a nucleic acid encoding a glucanase, and a method for using said nucleic acid in the assay.

Group XIII, claim 21 and 27, drawn to an assay for identifying functional interactors comprising a polypeptide (XII) with amino acid sequence in accordance with SEQ ID NO:1 or SEQ ID NO:2, and a method of using said polypeptide in an assay for identifying functional interactors.

Art Unit: 1636

Group XIV, claim 21, drawn to an assay for identifying functional interactors comprising an antibody against the protein toxin.

Groups XV, claim 23, drawn to a method of using a nucleic acid encoding a glucanase for finding variants by screening a gene library.

Groups XVI, claim 24, drawn to a method of using a polypeptide which is incorporated into a medium and combined with foods or animal feeds to identify or control harmful yeasts or fungi in said foods or feeds.

Group XVII, claim 25, drawn to a process for growing DSM 12864 and or DSM 12865 by growing said strains in synthetic B and or BAVC medium.

Group XVIII, claim 26, drawn to a method of using a nucleic acid encoding a glucanase for generation transgenic plants or plant cells.

PCT Rule 13.2 requires that unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups I-XVII do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The “special technical feature” of Group I is a protein toxin obtained from *Williposis californica* and or *Zygosaccharomyces bailii*, which is shown by Radler et al., 1993 (see abstract) to lack novelty or inventive step over the disclosed protein toxin, and does not make a contribution over the prior art. As such, this technical feature cannot link the invention as a whole to form a single general inventive concept under PCT Rule 13.1.

The invention of the remaining groups each has a unique technical feature not shared by the other groups. The special technical feature of Group II is a nucleic acid encoding a glucanase or protein toxin, which is not shared by the remaining groups. The special technical feature of Group III is a process for preparing the nucleic acid, which is not share by the remaining groups. The special technical feature of Group IV is a process for preparing the polypeptide, which is not shared by the remaining groups. The special technical feature of Group V is an antibody, which

Art Unit: 1636

is not shared by the remaining group. The special technical feature of Group VI-VIII is a drug product comprising the nucleic acid, polypeptide or an antibody, which is not shared by the remaining groups. The special technical feature of Group IX-XI is a diagnostic comprising the nucleic acid, polypeptide or an antibody, which is not shared by the remaining groups. The special technical feature of Group XII-XIV is an assay comprising the nucleic acid, polypeptide or an antibody, which is not shared by the remaining groups. The special technical feature of Group XV is a method of using the nucleic acid for screening library, which is not shared by the remaining groups. The special technical feature of Group XVI is a method for using a polypeptide to identify harmful yeast or fungi in food or feed, which is not shared by the remaining groups. . The special technical feature of Group XVII is a process for grow two yeast strains, which is not shared by the remaining groups. The special technical feature of Group XVIII is a method for using the nucleic acid for generating transgenic plant or plant cells, which is not shared by the remaining groups. Therefore, the unity of invention does not exist between the claims of Groups I-XVIII.

Groups I-XVI and XVIII are comprised of multiple inventions which are the products or methods drawn to different and distinct sequences which do not render obvious each other and lack ~~of~~ unity. If any of Groups I-XVI and XVIII is elected, applicants must elect a single invention which is the product or method drawn to one specific sequence to which the claims will be restricted. Note, this restriction to examination of a single sequence is due to the now very high and undue burden for examining more than one sequence which is caused by the continued exponential increase of size of the sequence databases to be searched for each sequence, resulting in a corresponding increase in computer search time and examiner time for

Art Unit: 1636

reviewing the computer search results. Therefore, the limited resources of the Office no longer permit examination of more than one sequence in an application.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1636

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine Qian, Ph.D.


ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER